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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/843,914 | 04/30/2001 | Bozidar Ferek-Petric | P-8191 | 9906 |

27581 7590 12/16/2002

MEDTRONIC, INC.
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EXAMINER

OROEZA, FRANCES P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3762

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|-----------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/843,914 | | FEREK-PETRIC, BOZIDAR | |
| | Examiner | | Art Unit | |
| | Frances P. Oropeza | | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2001 and 09 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims Pending

1. In this application, claims 1-36 are pending and claims 1, 8, 14, 20, 25 and 32 are independent.

Drawings

2. The corrected or substitute drawings were received on 1/9/02. These drawings are acceptable and have been entered into the record.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (US 5458622) in view of Bardy et al. (US 5257621).

Alt discloses an apparatus and method, substantially as claimed, to provide multiple threshold and therapy levels to successfully treat tachycardia (figure 4; c 9, ll 38-47; c 9, l 60 – c 10, l 19). The heart rate threshold increases and decreases based on the non-ECG sensor output (hemodynamic parameter / physiologically-sensed condition / hemodynamic measurement). When the heart rate (counted interval(s) / R-R interval(s)) is equal to or greater than a threshold or less than the threshold, a second threshold is adjusted and therapy is provided, as needed, to treat the tachycardia (c 11, ll 18-49; c 12, ll 5-28; c 13, ll 7-11; c 14, ll 44-51 and 56-61; c 15, ll

Art Unit: 3762

40-51). The intervals are consecutive, as non-consecutive intervals indicate dysrhythmia (c 5, ll 50-57; c 6, l 64 – c 7, l 5). (claims 1-4, 8-10, 14-16, 20, 21, 24-26, 31-33 and 36)

Resetting the threshold can comprises increasing or decreasing the threshold, based on the blood pressure feedback or based on a predetermined relationship between the physiologically-sensed condition. Inherently, the threshold is reduced with a reduction in blood pressure (c 5, ll 45-49; c 11, ll 35-44). (claims 6 and 13)

The hemodynamic sensor, the activity sensor (34), can also be an indirect sensor such as a sensor of blood pressure or a blood flow rate sensor (c 3, ll 12-26; c 7, l 64 – c 8, l 3; c 9, ll 47-52).

(claims 5, 7, 11, 12, 17, 18, 19, 22, 23, 27-30, 34 and 35)

As discussed in the previous paragraph, Alt discloses the claimed invention except for: using controller circuitry to initiate an adjustable number of intervals detected (NID) threshold, resetting the adjustable NID threshold based on at least a first measurement of a value (hemodynamic parameter / physiologically-sensed condition / a predetermined relationship / a hemodynamic measurement / a blood pressure measurement), and detecting tachycardia if the consecutive number of intervals satisfies / is equal to or greater than / the adjustable NID threshold. (claims 1, 3, 8, 13-15, 19, 20, 25, 32 and 33)

Bardy et al. disclose an apparatus for detection of, discrimination between and treatment of tachycardia and fibrillation and teach the following elements:

- use of control circuitry to identify a single value / R-R interval that detects tachyarrhythmias,
- use of subsequent values / R-R intervals to appropriately adjust the threshold level and therapy, wherein the threshold is adjusted by varying the number of intervals /

- R-R intervals for detection of tachycardia in each tachycardia rate zone, the threshold being a potentially unique number of intervals for each tachycardia rate zone, and
- use of measurements associated with the current heart rate / intervals for adjusting the number of intervals required to for detection of tachycardia, the measurements read to be a hemodynamic parameter /physiologically-sensed condition / hemodynamic measurement.

Modification of the PCD as taught by Alt with the elements above is motivated because use of less stringent criteria for tachycardia detection as the tachycardia event progresses enables the patient to receive more rapid effective treatment (c 17, ll 22-36; c 18, ll 1-43; c 19, ll 4-7).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JPO
12/10/02

[Signature]
JEFFREY R. JASTRZAB
PRIMARY EXAMINER
3762
12/11/02